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Recent Case

RECENT CASE

FOOD AND DRUG LAW—JUDICIAL LEGISLATION—BROADENING THE DEFINITION OF DRUG TO INCLUDE MEDICAL DEVICES

AMP Incorporated v. Gardner, No. 31829 (2d Cir., Feb. 13, 1968).

AMP Incorporated (AMP) developed two products which permit a new method of tying off, or ligating, severed blood vessels during surgery. The only way blood vessels could be ligated before these products were introduced was to hand-tie ligatures around severed vessels by means of a surgeon's knot. Both products consist of a disposable applicator, a nylon locking disk, and a nylon ligating loop. Nylon is currently used in ligatures requiring the hand-tying method. The disposable applicator can be either a hemostat or a thin tube. With the aid of the applicator, the severed vessel is closed by placing the nylon ligating loop around the vessel. The nylon ligature is threaded through the locking disk to form the loop. When the excess ligature material forming the loop is pulled through the disk, the ligature is tightened around the severed vessel. The disk then acts as a locking mechanism to keep the ligature secure. The excess thread is cut away by a blade which is an integral part of the applicator. The locking disk and ligating thread remain in the body.

AMP requested that its products be classified by the Food and Drug Administration (FDA). The FDA advised AMP that the products were "new drugs." AMP felt that the products were "devices" within the meaning of the Federal Food, Drug and Cosmetic Act[1] (Act) and not "drugs"[2] or "new drugs"[3] as defined by the Act. AMP began to follow the provisions of the Act pertaining to devices. Because the FDA threatened seizure if AMP did not comply with the "drug" and "new drug" provisions, AMP sought a judgment declaring its products "devices" and an injunction barring seizure of its products. The District Court for the Southern District of New York determined that the products should be classified as "new drugs" and granted summary judgment to defendants.[4] The Second Circuit affirmed in *AMP Incorporated v. Gardner*.[5]

1. Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h) (1938).
2. Food, Drug and Cosmetic Act, 21 U.S.C. § 321(g) (1938).
3. Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p) (1938).
4. AMP Incorporated v. Gardner, 275 F. Supp. 410 (S.D.N.Y. 1967).
5. No. 31829 (2d Cir., Feb. 13, 1968).

Two questions were presented in this case. First, were the products "drugs" or "devices"? Second, if they were "drugs," were they "new drugs"? Devices and standard approved drugs may be placed into interstate commerce without the approval of the Secretary of Health, Education and Welfare. "New drugs," however, must go through rigorous approval procedures established by the government[6] which may delay production for several years. AMP was therefore interested in having its product classified as a "device."

From the outset the court of appeals assumed *arguendo* that the disposable applicators were devices. The nylon ligating thread and locking disk were the components which the court felt created the controversy.[7] The current relevant provisions of section 321 of the Act defining "drug," "device" and "new drug" are as follows:

> (g) (1) The term "drug" means
> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
> (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
> (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
> (D) articles intended for use as a component of any article specified in clause (A), (B), or (C) of this paragraph; *but does not include devices or their components, parts, or accessories.*[8]
>
> . . . .
>
> (h) The term "device" . . . means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended
> (1) for use in the diagnosis, cure, mitigation, treat-

6. Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a)-(i) (1938). These subsections of section 355 require any person who wants to introduce a new drug into interstate commerce to file an application with the FDA and to get approval from the Secretary of Health, Education and Welfare before the drug may be marketed. Once the drug has been approved it may be shipped without filing subsequent applications. Devices need no such approval.

Devices and drugs which have received approval are both regulated, however, under sections 351, pertaining to adulterated drugs and devices; 352, pertaining to misbranded drugs and devices; and 353, pertaining to exemptions of drugs and devices. Thus, a device which is adulterated or misbranded may be seized and taken out of interstate commerce by the FDA.

7. No. 31829 (2d Cir. 1968) at 4.

8. Food, Drug and Cosmetic Act, 21 U.S.C. § 321(g) (1938) (emphasis added).

ment, or prevention of disease in man or other animals; or

(2) to affect the structure or any function of the body of man or other animals.[9]

. . . .

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . . or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.[10]

Nylon sutures are listed in the official *United States Pharmacopoeia*.[11] Thus, it would appear that nylon ligatures are drugs because the Act defines drugs as articles recognized in the *Pharmacopoeia*.[12] A complete reading of the section defining a drug, however, shows that devices are specifically exempted from the definition.[13] Therefore, even if the article is listed in the *Pharmacopoeia*, it may be a device and not a drug. The reasoning becomes circuitous. The definition of a drug or a device can only be obtained from statutory interpretation based upon legislative history.

The plain meaning of the provision defining a drug clearly indicates that drugs and devices are mutually exclusive. A drug cannot also be a device. The district court said that the ligating loop and disk "are arguably either articles or instruments, apparatus and contrivances . . . capable of coming within [the] two definitions, [drug and device]. . . ."[14] This reasoning is clearly erroneous

9. Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h) (1938).
10. Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p) (1938).
11. UNITED STATES PHARMACOPOEIA 691 (17th rev. ed. 1965).
12. Food, Drug and Cosmetic Act, 21 U.S.C. § 321(g)(1)(A) (1938).
13. Food, Drug and Cosmetic Act, 21 U.S.C. § 321(g)(1)(D) (1938).
14. AMP Incorporated v. Gardner, 275 F. Supp. 410, 414 (S.D.N.Y. 1967). Supporting the contention that a device *cannot* arguably be a drug is a discussion on the floor of the Senate between Senator Clark (Missouri) and Senator Copeland (New York), who introduced the bill. Senator Clark:

> Mr. President, I should like to ask the Senator from New York how he can reconcile the language of this section and the language of the amendment with the common, ordinary acceptation of the English language. In other words, here he says it is proper to describe as a drug "all substances, preparations, and devices intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." In other words, if a

since devices are explicitly excluded from the definition of a drug. The actual point of interpretation, as the court of appeals recognized, was how broad the definition of a drug should be. AMP was contending that the nylon thread and disk were component parts of an admitted device, the applicator, thereby making them devices.[15] The FDA was contending that the applicator was a component part of the nylon thread and disk, allegedly drugs, thereby

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man has invented a shoulder brace, a purely mechanical device, which he claims will straighten a man's shoulders and expand his chest and make for his health, according to the definition contained in this paragraph it has to be described as a drug and treated in law as a drug.

74 CONG. REC. 4841 (1935) (remarks of Senator Clark). In these remarks Senator Clark was referring to S. 5, 74th Cong., 1st Sess. (1935), which did not then distinguish between drugs and devices. The predecessors of S. 5 also did not make such a distinction. S. 2800, 73d Cong., 2d Sess. (1934); S. 2000, 73d Cong., 2d Sess. (1934); S. 1944, 73d Cong., 1st Sess. § 2(b) (1933).

Senator Copeland answered Senator Clark by saying:

The Senator from New York would have no objection to the proposal about the particular devices mentioned by the Senator. But there are on the market a great many devices which are offered for use, and citizens are exploited believing that they can be cured of all sorts of ailments by the use of them. For example, there is such a thing as a radium belt carrying a disk alleged to contain radium; it is claimed that if the Senator from Missouri should wear that belt he would never have appendicitis or gallbladder disease or perhaps any other ailment.

74 CONG. REC. 4841 (1935) (remarks of Senator Copeland).

Senator Clark replied:

Speaking for myself alone, I have no disposition to attack every word in the bill; but we are legislating on a very important matter. As I see it, what the Senator from New York is doing in this particular case is the same thing as if the Congress of the United States should attempt to say by law that calling a sheep's tail a leg would make it a leg. In other words, the Senator from New York in this language is attempting to define a wholly mechanical device as a drug. I say it is bad legislation; that if he desires to legislate against these mechanical devices he ought to do it in the open instead of indirection and attempting to define as a drug something which palpably is not a drug.

74 CONG. REC. 4841 (1935) (remarks of Senator Clark).

I am opposed to enacting an absurdity. It is absurd to declare a device a drug to begin with, and it is still more absurd to declare such a device as a scale a drug.

74 CONG. REC. 4843 (1935) (remarks of Senator Clark).

My objection goes to putting the Congress of the United States in the ridiculous, absurd, and asinine position of defining a purely mechanical device as a "drug." My objection to this particular amendment is to taking in the bill that ridiculous position and embodying in it such a definition.

74 CONG. REC. 4844, 4845 (1935) (remarks of Senator Clark). Seemingly as a result of this exchange the bill was amended as S. 5, 75th Cong., 1st Sess. (1937), the current enactment which distinguishes between drugs and devices. For a discussion of this amendment see DUNN, FEDERAL FOOD, DRUG AND COSMETIC ACT— A STATEMENT OF ITS LEGISLATIVE RECORD 477 (1938).

15. *See* AMP Incorporated v. Gardner, No. 31829 (2d Cir. 1968) at 4 n.3, 10 n.13.

making the entire product a drug within the meaning of the Act.[16]

In this matter of definition certain quotations from the legislative history of the Act are pertinent. During hearings on the bill which was finally enacted, Dr. William C. Woodward, then Legislative Counsel for the American Medical Association, was asked what the term "devices" included. He answered:

> The term is broad enough to include—well, we will say trusses. I would say it is broad enough to include eyeglasses, checking up on the lenses; and clinical thermometers, possibly; *catgut used in surgical work; surgical instruments;* particularly, however, electrical devices, ultraviolet ray devices, and things of that sort; electrical belts, and a thousand and one things that are sold at the present time without any regulation at all and that are utterly fraudulent.[17]

These remarks went unchallenged by the subcommittee. Although catgut was specifically mentioned, the witness emphasized the "quack" devices which, at the time the Act was passed, were polluting the country. Indeed, when Senator Copeland introduced a predecessor of the final bill, he noted that these quack devices had to be controlled.[18] The importance attached to quack devices prompted the court of appeals to say in regard to the separate definitions of drugs and devices:

> We have found nothing in the legislative history of the Act indicating that the Congressional purpose in providing a separate definition of "devices" was anything other than to avoid the incongruity of classifying such things as electric belts as "drugs." There was at the time no practical significance to the distinction between "drugs" and "devices" for the operative provisions of the bill (*e.g.*, the provision barring the introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded) applied identically to both.[19]

This language does not say that a drug could also be a device. It

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16. *Id.*

17. *Hearings on H.R. 6906, H.R. 8805, H.R. 8941, and S. 5 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 74th Cong., 1st Sess., 319-20 (1935).

18. Senator Copeland:

> The present law defines drugs as substances or mixtures of substances intended to be used for the cure, mitigation, or prevention of disease. This narrow definition permits escape from legal control of all therapeutic or curative devices like electric belts, for example. It also permits the escape of preparations which are intended to alter the structure or some function of the body, as for example, preparations intended to reduce excessive weight. There are many worthless and some dangerous devices and preparations falling within these classifications. S. 2800 contains ample authority to control them.

78 CONG. REC. 8960 (1934) (remarks of Senator Copeland).

19. No. 31829 (2d Cir. 1968) at 7.

only suggests that at the time of passage of the Act drugs and devices were regulated by the same provisions of the Act.

A practical distinction soon developed, however, with the passage of the "new drug" provisions which require government approval before new drugs can be introduced into interstate commerce.[20] The Act contains no similar provision for new devices. The court of appeals answered this problem by noting that the "new drug" provisions were not incorporated until after the definitions had been drawn up.[21] Therefore the court reasoned that the term "new drug" was used "without any attention to the fact that the distinction between 'drug' and 'device' had thus for the first time become important."[22] The court recognized that the only significance in classifying the product as a "device" instead of a "drug" was to avoid the "new drug" provisions if the product was a drug. Since this was the only importance attached to the distinction, the court looked to policy in making its decision and found it in the noble, but unsubstantiated, need to protect the unknowing public's health. AMP's products were "drugs" and not "devices" because the purpose of the Act was "to keep inadequately tested medical and related products which might cause widespread danger to human life out of interstate commerce."[23]

After the court determined that the products were "drugs," it held that they were also "new drugs." The reasoning was that although nylon sutures had been in use for an extended period, the novel means of employing the nylon thread and nylon disk made them new drugs.[24] To support its rationale for classifying the products as drugs, the court expressed the policy reasons for considering them to be "new drugs": "We would, moreover, be reluctant to give a narrow construction to this statute [referring to the "new drug" provisions], touching the public health as it does."[25] Although the court acknowledged that the "new drug" provisions were precipitated by the death of several persons after using "Elixir Sulfanimide,"[26] a drug in the pharmacological sense, it con-

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20. Food, Drug and Cosmetic Act, 21 U.S.C. § 355 (1938).

21. No. 31829 (2d Cir. 1968) at 8. *See also* DUNN, FEDERAL FOOD, DRUG AND COSMETIC ACT—A STATEMENT OF ITS LEGISLATIVE RECORD 1316-27 (1938).

22. No. 31829 (2d Cir. 1968) at 8.

23. *Id.*

24. *Id.* at 4 n.3:

> The applicator is the embodiment of a new method of applying the ligature, which is the basis of the defendants' "new drug" conclusion. 21 C.F.R. § 130.1(h) provides: "The newness of a drug may arise by reason (among other reasons) of: . . . (5) The newness of a dosage, or method or duration of administration or application. . . ." *And see* Merritt Corp. v. Folsom, 165 F. Supp. 418, 421 (D. D.C. 1958).

25. *Id.* at 9.

26. *Id.* at 8-9.

cluded that congressional intent must have been to give the words the broadest possible meaning. The court's final interpretation was that "[t]he exclusionary classification 'devices' should, we think, be limited to such things as Congress expressly intended it to cover."[27] Hence "devices" would now apparently include the quack devices and such things as office scales and, from this opinion, hemostats and long thin tubes.[28] Beyond that only students of legislative history should tread.

This opinion merits comment for its questionable reasoning which borders on judicial legislation. The same court of appeals has said concerning statutory interpretation: "What is more to the point, as we are in this case interpreting legislative enactment, it is our duty to try to discover and carry out the legislative purpose, not to inject our own notions of desirable policy. . . ."[29] The court in this decision has not taken its own advice. By stating that the only things which are "devices" within the meaning of the Act are those things specifically intended to be so by Congress, the court has opened the door to a flood of litigation because of the vagueness of the phrase. Now certain devices, not specifically intended by Congress to be devices, are drugs—but which devices? The AMP loop and disk perform a purely mechanical operation; they are, however, left in the body. Is the test—articles which are left in the body are drugs? Certainly, this test would seem to protect the public health of which the court of appeals spoke. In this particular case, however, the "public danger" cry is a bark without a bite. Both AMP and the FDA agreed that there had never been a reported case of an implant in the human body causing any carcinogenic effect, including schrapnel, pins, sutures and ligatures.[30]

A bill introduced in the House of Representatives on June 8, 1967, which is supported by the FDA, is entitled: "A Bill to protect the public health by amending the Federal Food, Drug and Cosmetic Act to assure the safety, reliability, and effectiveness of medical devices."[31] This bill proposes government approval of devices before they are marketed. Included under "therapeutic

27. *Id.* at 9.

28. At page 4 of the opinion, the court assumes *arguendo* that the applicators are devices. Two other cases have made the drug-device distinction. In one a metal pin that was to be left in the body was determined to be a "device" within the meaning of the current Act. *See* Orthopedic Equip. Co. v. Eutsler, 276 F.2d 455 (4th Cir. 1960). In the other case gauze bandages were found to be a "drug." This case, however, was decided prior to passage of the current act when no distinction was made between drugs and devices. *See* United States v. 48 Dozen Packages of Gauze Bandage, 94 F.2d 641 (2d Cir. 1938).

29. Ingo v. Koch, 127 F.2d 667, 678 (2d Cir. 1942).

30. Brief for Appellant at 13, AMP Incorporated v. Gardner, No. 31829 (2d Cir., Feb. 13, 1968).

31. H.R. 10726, 90th Cong., 1st Sess. (1967) (excerpt from the preamble).

devices" are devices "intended to be secured or otherwise placed, in whole or in part, *within the human body* or into a body cavity, or directly in contact with mucous membrane, *and is intended to be left in the body* or such cavity, or in such direct contact, permanently, indefinitely, or for a substantial period or periods."[32] It is strange indeed that the Congress which thirty years ago included ligatures and other devices to be left in the body within its "drug" and "new drug" definitions should move for double coverage under a new provision. The logical inference, of course, is that the Act does not currently include such mechanical devices in its "drug" definition. Since they are not so included, neither can they be "new drugs." It would appear that the Second Circuit has hastened the legislative process.

The better reasoning in this case would have been to recognize that the AMP products performed a purely mechanical operation, thereby making them devices. By so doing the court would not have had to strain to find that public policy distinguished a drug from a device. The court has substantially expanded the power of the FDA by allowing more products to come within the "new drug" provisions. From a policy viewpoint this may not be a bad result, but there is no basis in law for the decision. The better course would have been a plea to the legislature and a recognition of judicial limitation.

GARY R. MYERS

32. *Id.* at 7 (emphasis added).

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